Medtronic

Surgical Technique

Anatomic PEEK™ Cervical Fusion System

with Nanotechnology

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Product information

Anatomic PEEK™ cervical fusion system with Nanotechnology is a system of intervertebral spacers and instruments for implantation. The upper and lower surfaces of each implant incorporate a three-dimensional titanium scaffold with interconnected pores averaging 523 µm, and pore interconnections averaging 229 µm in diameter.

This product demonstrates the requirements for nanotechnology. The surface has been deliberately manipulated to produce nanoscale dimensions which exhibit specific properties. The scaffold of the Anatomic PEEK™ devices is electrochemically treated to possess a controlled nanotopography composed of nanotube arrays having a pore size diameter between 30-90 nanometers. Calcium and phosphate are incorporated into the nanotube surface. These nanotube arrays have been shown to increase and accelerate calcified extracellular matrix production in vitro1 (**Figure 1** and **Figure 2**). The scaffold with nanotubes assists in securing the implant in the intervertebral space and provides radiographic confirmation of the implant location.

The Anatomic PEEK™ cervical implant has a trapezoidal shape and a large vertical cavity which is packed with bone graft material to promote fusion of the adjacent vertebral bodies. The implant is available in a variety of sizes to accommodate variations in individual patient anatomy. The Anatomic PEEK™ devices are manufactured from polyetheretherketone (PEEK-OPTIMA™) per ASTM F2026. The integral scaffold (OsteoSync) is manufactured from CP titanium as described by ASTM F67.

Human Osteoblast Mineralization, Day 21, CP Titanium substrate

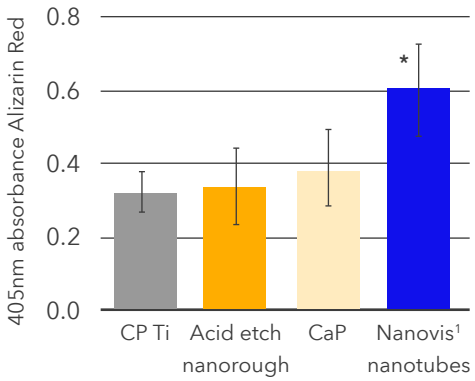

Figure 1 In vitro osteoblast mineralization on material surfaces: *Nanovis' nanotubes versus "as machined" commercially pure titanium (CP Ti), Acid etch nanorough and Calcium Phosphate (CaP) p<0.0001.

Human MSC Mineralization, Day 21, CP Titanium substrate

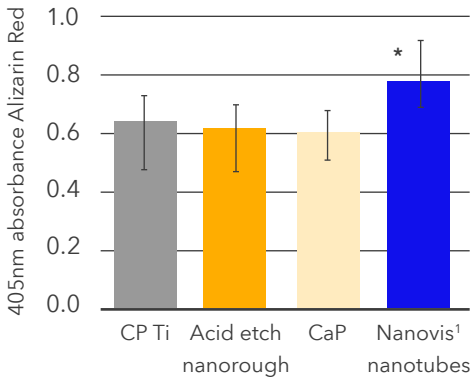

Figure 2 In vitro mesenchymal stem cell (MSC) mineralization on material surfaces: *Nanovis' nanotubes versus "as machined" commercially pure titanium (CP Ti), Acid etch nanorough and Calcium Phosphate (CaP) p<0.005.

In vitro performance may not be representative of clinical performance.

1 Data on file, available from Nanovis Spine.

Surgical site access and disc preparation

Perform surgical site access and disc preparation per the surgeon's usual manner. The main goal is to remove extruded fragments, decompress neural elements, and provide entry into the disc space for distraction, with minimal or no nerve root retraction.

Note

Patient must be properly positioned and/or stabilized during surgery, per the surgeon's chosen approach.

To ensure proper fusion below and around the location of the implant, autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate must be used. Pre-pack the disc space per the surgeon's usual manner, taking into consideration patient specific needs.

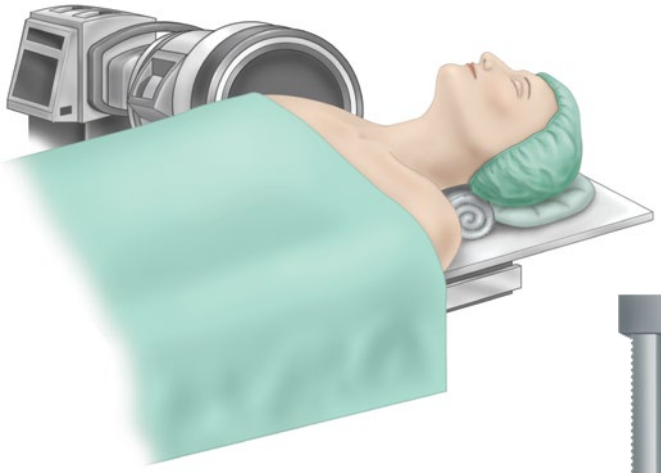

Figure 1

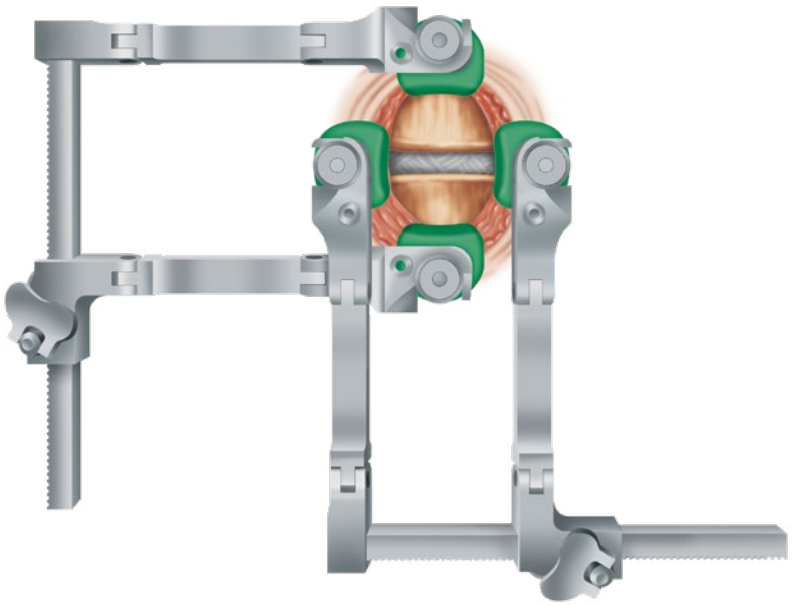

Figure 2

Trialing and final disc prep

Once the decompression and end-plate preparation are completed, determine the Anatomic PEEK™ with nanotechnology implant sizing by selecting the lordotic trial that provides the most satisfactory fit in the prepared disc space.

The trials come in three "footprints;" 14 mm wide × 11 mm deep (purple trials), 16 mm wide × 14 mm deep (green trials), and 18 mm wide × 16 mm deep (blue) in both 4.6 and 10 degree offerings.

Note

An implant of the same lordosis as the trial should be used.

Select the footprint that best matches the width and depth of the prepared interbody space.

The trial should fit flush against the end plates and produce a tight interference fit while restoring and maintaining adequate interbody height.

Sequentially trial, until the desired fit is achieved.

The trials for use with the Anatomic PEEK™ cervical fusion system will match the geometry of the cervical spacers in the system.

As needed, use fluoroscopy to confirm proper placement.

If desired, additional end-plate preparation may be carried out with a rasp. There are three rasps offered within the system, one in each of

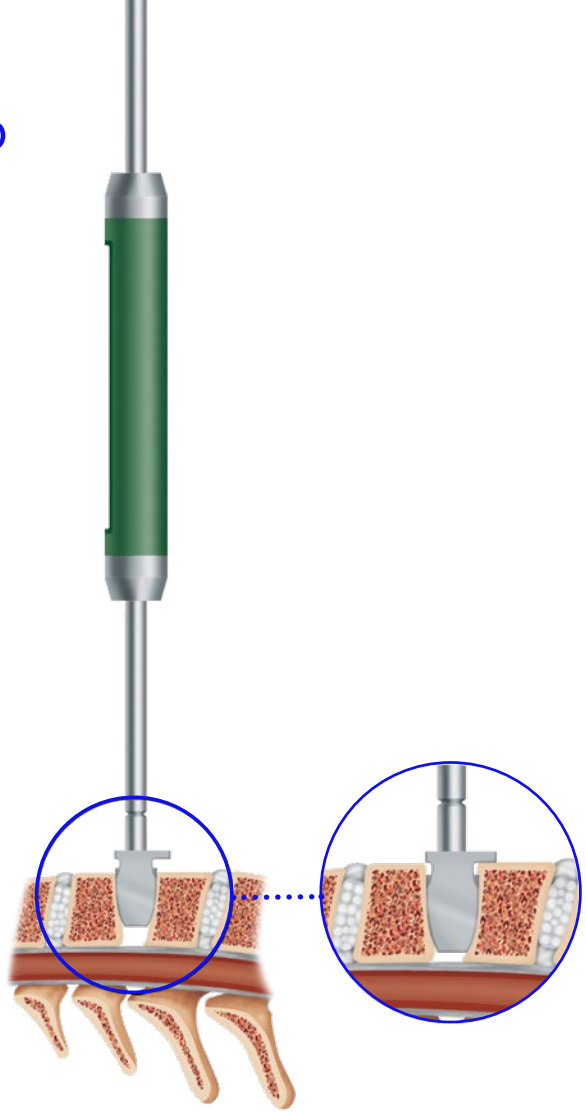

Figure 3

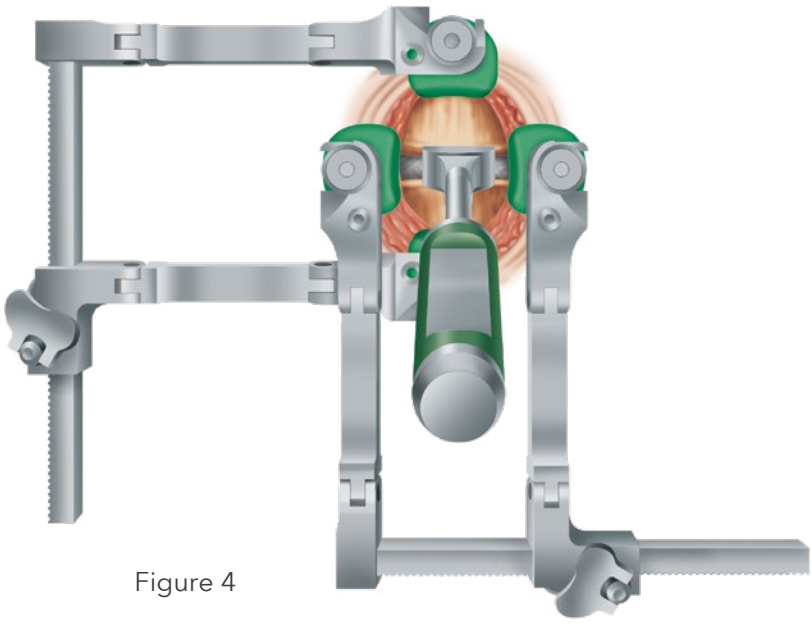

Figure 4

Implantation

the same footprints as the trial. Select the rasp that will decorticate the end plates with minimal bone removal.

Attaching the Implant to the Inserter

Select the Anatomic PEEK™ cervical fusion spacer with nanotechnology that corresponds to the final trial.

To attach, align the implant to the inserter and push the implant onto the inserter assembly applying positive pressure.

Rotate the inserter inner sleeve clockwise until the implant is fully seated and firmly attached to the inserter before inserting.

The center of the implant must be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone, such as Grafton™ DBF bone graft, with bone marrow aspirate.

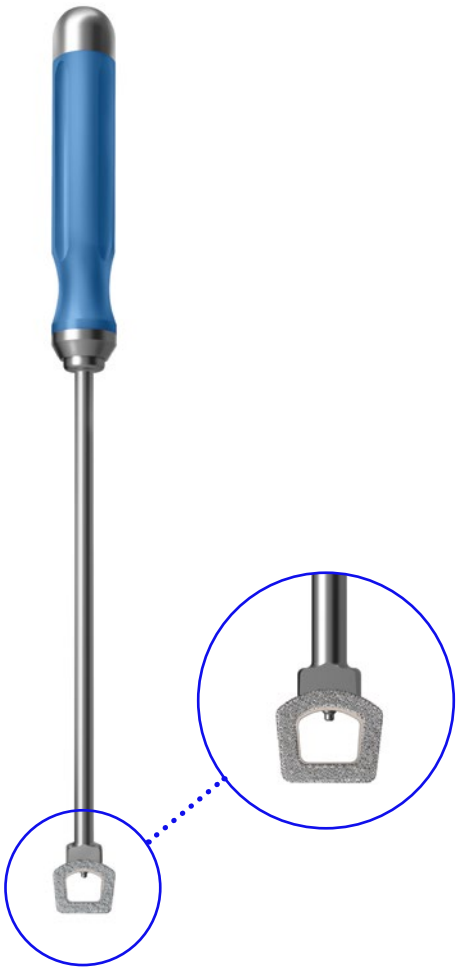

Figure 5

Implant positioning

The directional arrows on the anterior surface of the spacer should point superiorly.

The implant is introduced into the prepared interbody space and gently tapped into position using a mallet.

A tamp may be used for final positioning.

If necessary, the spacer can be repositioned by reattaching the threaded inserter.

Post-implantation steps

Confirm the final position of the implant with fluoroscopy.

After the Anatomic PEEK™ implant with nanotechnology is placed, additional graft may be placed around the cage as desired.

Note

The Anatomic PEEK™ cervical fusion system with nanotechnology is to be used with supplemental fixation, the hyperlordotic implants (≥ 10°) are required to be used with an anterior cervical plate.

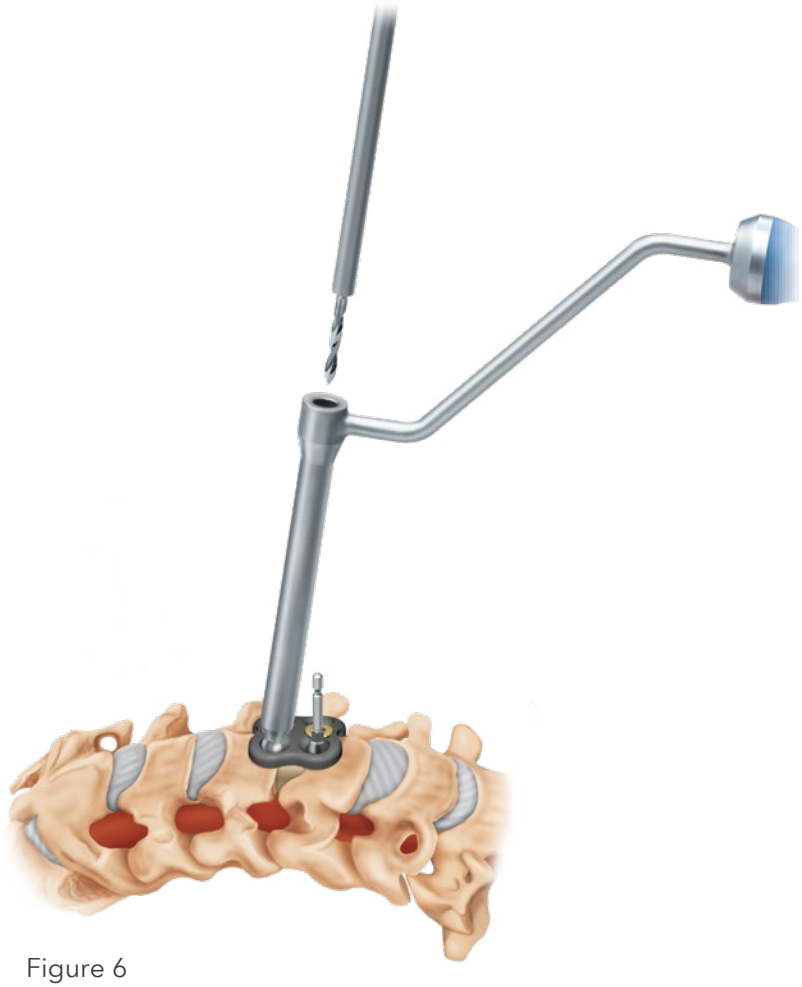

Figure 6

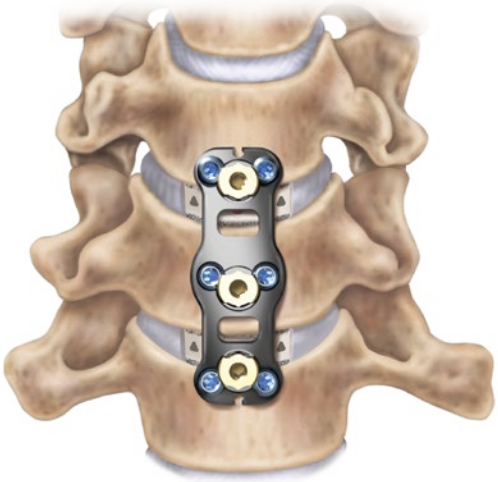

Figure 7

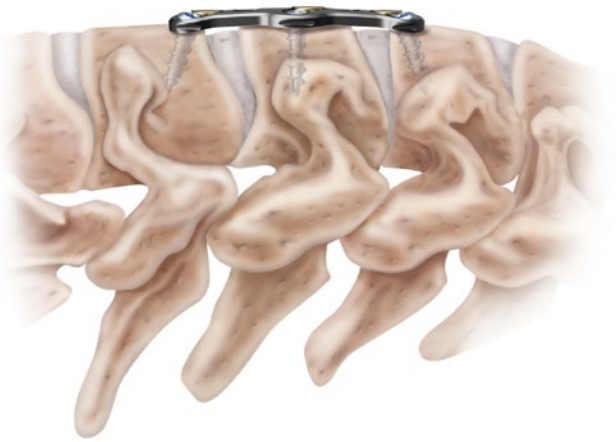

Figure 8

Explantation

The spacer can be removed intact by exposing the anterior surface of the implant and creating a clear plane around the implant.

The implant inserter/holder can then be reattached to the spacer, and the implant can be removed intact with an in-line slap hammer.

Note

Distraction and bone removal may also be required before the implant can be removed.

Product ordering information

Anatomic PEEK™ Cervical Fusion System with Nanotechnology

SPS03242 4.6° Implants

CFN	Description	Qty
3240541	Anatomic PEEK™ 4.6° Spacer with nanotechnology 14 mm × 11 mm × 5 mm	2
3240641	Anatomic PEEK™ 4.6° Spacer with nanotechnology 14 mm × 11 mm ×6 mm	3
3240741	Anatomic PEEK™ 4.6° Spacer with nanotechnology 14 mm × 11 mm × 7 mm	3
3240841	Anatomic PEEK™ 4.6° Spacer with nanotechnology 14 mm × 11 mm × 8 mm	3
3240941	Anatomic PEEK™ 4.6° Spacer with nanotechnology 14 mm × 11 mm × 9 mm	2
3240041	Anatomic PEEK™ 4.6° Spacer with nanotechnology 14 mm × 11 mm × 10 mm	1
3240564	Anatomic PEEK™ 4.6° Spacer with nanotechnology 16 mm × 14 mm × 5 mm	2
3240664	Anatomic PEEK™ 4.6° Spacer with nanotechnology 16 mm × 14 mm × 6 mm	3
3240764	Anatomic PEEK™ 4.6° Spacer with nanotechnology 16 mm × 14 mm × 7 mm	3
3240864	Anatomic PEEK™ 4.6° Spacer with nanotechnology 16 mm × 14 mm × 8 mm	3
3240964	Anatomic PEEK™ 4.6° Spacer with nanotechnology 16 mm × 14 mm × 9 mm	2
3240064	Anatomic PEEK™ 4.6° Spacer with nanotechnology 16 mm × 14 mm × 10 mm	1
3240586	Anatomic PEEK™ 4.6° Spacer with nanotechnology 18 mm × 16 mm × 5 mm	2
3240686	Anatomic PEEK™ 4.6° Spacer with nanotechnology 18 mm × 16 mm × 6 mm	3
3240786	Anatomic PEEK™ 4.6° Spacer with nanotechnology 18 mm × 16 mm × 7 mm	3
3240886	Anatomic PEEK™ 4.6° Spacer with nanotechnology 18 mm × 16 mm × 8 mm	3
3240986	Anatomic PEEK™ 4.6° Spacer with nanotechnology 18 mm × 16 mm × 9 mm	2
3240086	Anatomic PEEK™ 4.6° Spacer with nanotechnology 18 mm × 16 mm × 10 mm	1

SPS03243 10° Implants

CFN	Description	Qty
3200541	Anatomic PEEK™ 10° Spacer with nanotechnology 14 mm × 11 mm × 5 mm	2
3200641	Anatomic PEEK™ 10° Spacer with nanotechnology 14 mm × 11 mm × 6 mm	3
3200741	Anatomic PEEK™ 10° Spacer with nanotechnology 14 mm × 11 mm × 7 mm	3
3200841	Anatomic PEEK™ 10° Spacer with nanotechnology 14 mm × 11 mm × 8 mm	3
3200941	Anatomic PEEK™ 10° Spacer with nanotechnology 14 mm × 11 mm × 9 mm	2
3200041	Anatomic PEEK™ 10° Spacer with nanotechnology 14 mm × 11 mm × 10 mm	1
3200564	Anatomic PEEK™ 10° Spacer with nanotechnology 16 mm × 14 mm × 5 mm	2
3200664	Anatomic PEEK™ 10° Spacer with nanotechnology 16 mm × 14 mm × 6 mm	3
3200764	Anatomic PEEK™ 10° Spacer with nanotechnology 16 mm × 14 mm × 7 mm	3
3200864	Anatomic PEEK™ 10° Spacer with nanotechnology 16 mm × 14 mm × 8 mm	3
3200964	Anatomic PEEK™ 10° Spacer with nanotechnology 16 mm × 14 mm × 9 mm	2
3200064	Anatomic PEEK™ 10° Spacer with nanotechnology 16 mm × 14 mm × 10 mm	1
3200586	Anatomic PEEK™ 10° Spacer with nanotechnology 18 mm × 16 mm × 5 mm	2
3200686	Anatomic PEEK™ 10° Spacer with nanotechnology 18 mm × 16 mm × 6 mm	3
3200786	Anatomic PEEK™ 10° Spacer with nanotechnology 18 mm × 16 mm × 7 mm	3
3200886	Anatomic PEEK™ 10° Spacer with nanotechnology 18 mm × 16 mm × 8 mm	3
3200986	Anatomic PEEK™ 10° Spacer with nanotechnology 18 mm × 16 mm × 9 mm	1
3200086	Anatomic PEEK™ 10° Spacer with nanotechnology 18 mm × 16 mm × 10 mm	1

Product ordering information continued

SPS02037 Anatomic PEEK™ Instrument Set

Product Number	Description
6246011	Inserter Handle
6279017	Threaded Inner Shaft
6246041	Rasp 14 mm × 11 mm
6246064	Rasp 16 mm × 14 mm
875-725	Curved Tamp
6472061	Mallet
6279004	Caliper
6248541	Trial 14 mm × 11 mm, 5 mm
6248641	Trial 14 mm × 11 mm, 6 mm
6248741	Trial 14 mm × 11 mm, 7 mm
6248841	Trial 14 mm × 11 mm, 8 mm
6248941	Trial 14 mm × 11 mm, 9 mm
6248041	Trial 14 mm × 11 mm, 10 mm
6248141	Trial 14 mm × 11 mm, 11 mm
6248241	Trial 14 mm × 11 mm, 12 mm
6248564	Trial 16 mm × 14 mm, 5 mm
6248664	Trial 16 mm × 14 mm, 6 mm
6248764	Trial 16 mm × 14 mm, 7 mm
6248864	Trial 16 mm × 14 mm, 8 mm
6248964	Trial 16 mm × 14 mm, 9 mm
6248064	Trial 16 mm × 14 mm, 10 mm
6248164	Trial 16 mm × 14 mm, 11 mm
6248264	Trial 16 mm × 14 mm, 12 mm
6248364	Trial 16 mm × 14 mm, 13 mm
6248464	Trial 16 mm × 14 mm, 14 mm
6240004	Anatomic Upper Tray
6240005	Anatomic Lower Tray
6240007	Anatomic Lid
6240008	Anatomic Case

Product ordering information continued

SPS03244 Anatomic nanoPEEK 10° Trial Set

CFN	Description	Qty
6208541	Anatomic PEEK™ 10° Trial 14 mm × 11 mm × 5 mm	1
6208641	Anatomic PEEK™ 10° Trial 14 mm × 11 mm × 6 mm	1
6208741	Anatomic PEEK™ 10° Trial 14 mm × 11 mm × 7 mm	1
6208841	Anatomic PEEK™ 10° Trial 14 mm × 11 mm × 8 mm	1
6208941	Anatomic PEEK™ 10° Trial 14 mm × 11 mm × 9 mm	1
6208041	Anatomic PEEK™ 10° Trial 14 mm × 11 mm × 10 mm	1
6208564	Anatomic PEEK™ 10° Trial 16 mm × 14 mm × 5 mm	1
6208664	Anatomic PEEK™ 10° Trial 16 mm × 14 mm × 6 mm	1
6208764	Anatomic PEEK™ 10° Trial 16 mm × 14 mm × 7 mm	1
6208864	Anatomic PEEK™ 10° Trial 16 mm × 14 mm × 8 mm	1
6208964	Anatomic PEEK™ 10° Trial 16 mm × 14 mm × 9 mm	1
6208064	Anatomic PEEK™ 10° Trial 16 mm × 14 mm × 10 mm	1
6208586	Anatomic PEEK™ 10° Trial 18 mm × 16 mm × 5 mm	1
6208686	Anatomic PEEK™ 10° Trial 18 mm × 16 mm × 6 mm	1
6208786	Anatomic PEEK™ 10° Trial 18 mm × 16 mm × 7 mm	1
6208886	Anatomic PEEK™ 10° Trial 18 mm × 16 mm × 8 mm	1
6208986	Anatomic PEEK™ 10° Trial 18 mm × 16 mm × 9 mm	1
6208086	Anatomic PEEK™ 10° Trial 18 mm × 16 mm × 10 mm	1
6208010	Anatomic PEEK™ Trials Tray/Lid	1

Important Information on the Anatomic PEEK™ Cervical Fusion System with Nanotechnology

Purpose
Anatomic PEEK™ cervical fusion system with nanotechnology devices including those with macro-, micro-, and nano-roughened surface textured features are indicated for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1.

These patients should have had at least six weeks of non-operative treatment. The Anatomic PEEK™ device is to be used with supplemental fixation; the hyperlordotic implants (≥10°) are required to be used with an anterior cervical plate. The Anatomic PEEK™ cervical fusion system with nanotechnology is also required to be used with autogenous bone and/or

allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate, and is to be implanted via an open anterior approach.

Description
The Anatomic PEEK™ cervical fusion system with nanotechnology consists of implants and instruments for implantation. The upper and lower surfaces of the implant incorporate a three-dimensional titanium scaffold with interconnected pores averaging 523 µm, and pore interconnections averaging 229 µm in diameter.

This product demonstrates the requirements for nanotechnology. The surface has been deliberately manipulated to produce nanoscale dimensions which exhibit specific properties. The scaffold of the Anatomic PEEK™ devices is electrochemically treated to possess a controlled nanotopography composed of nanotube arrays having an average pore size between 30-90 nanometers. Calcium and phosphate are incorporated into the nanotube surface. The scaffold with nanotubes assists in securing the implant in the intervertebral space and provides radiographic confirmation of the implant location.

The Anatomic PEEK™ devices are available in a variety of sizes to accommodate the individual anatomic and clinical circumstances of each patient.

Indications
Anatomic PEEK™ cervical fusion system with nanotechnology devices including those with macro-, micro-, and nano-roughened surface textured features are indicated for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. These patients should have had at least six weeks of non-operative treatment. The Anatomic PEEK™ device is to be used with supplemental fixation; the hyperlordotic implants (≥ 10°) are required to be used with an anterior cervical plate. The Anatomic PEEK™ cervical fusion system with nanotechnology is also required to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate, and is to be implanted via an open anterior approach.

Contraindications
The Anatomic PEEK™ cervical fusion system with nanotechnology device is not intended for posterior surgical implantation. Contraindications include:

- Any medical or surgical condition which would preclude the potential benefit of spinal implantsurgery such as the presence of tumors or congenital abnormalities, elevation of sedimentationrate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shiftin the WBC differential count.
- Any patient having inadequate tissue coverage over the operative site or where there isinadequate bone stock, bone quality, or anatomical definition.
- Any patient unwilling to cooperate with postoperative instructions.
- Fever or leukocytosis.
- Infection local to the operative site and/or signs of local inflammation.
- Mental illness.
- Morbid obesity.
- Pregnancy.
- Any case not requiring fusion.
- Suspected or documented allergy or intolerance to the component materials.
- This device must not be used for pediatric cases.
- Patients with a known hereditary or required bone friability or calcification problem should notbe considered for this type of surgery.
- Prior fusion at the level to be treated.
- Any patient in which implant use would interfere with anatomical structures or expectedphysiological performance.
- Any case that requires the mixing of metals from two different components or systems.

Nota bene: although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- Severe bone resorption
- Osteomalacia
- Severe osteoporosis

Potential adverse events
The following potential adverse events are associated with spinal fusion surgery and may occur with use of the Anatomic PEEK™ implants:

- Nonunion, delayed union.
- Infection, early or late.
- Breakage of the device.
- Pressure on the surrounding tissue or organs.
- Loss of proper spinal curvature, correction, height, and/or reduction.
- Decreased bone density due to stress shielding at, above, or below the level of surgery.
- Early or late loosening or movement of the device.
- Degenerative changes or instability of segments adjacent to fused vertebral levels.
- Scarring.
- Fracture, microfracture, resorption, damage or penetration of any spinal bone (includingpedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/orbelow the level of surgery. Retropulsion of bone graft.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level ofsurgery.
- Loss of or increase in spinal mobility or function.
- Inability to resume activities of normal daily living.
- Cessation of any potential growth of the operated portion of the spine.
    - Discomfort or abnormal sensation due to the surgical procedure or presence of the device.
- Implant material sensitivity, or allergic reaction to a foreign body.
- Discitis, arachnoiditis, and/or other types of inflammation.

Important Information on the Anatomic PEEK™ Cervical Fusion System with Nanotechnology

- Bone graft donor site complication.
- Complications associated with requisite fixation such as construct loosening or breakage, orsensitivity to the material of the selected fixation system.
- Urinary retention or loss of bladder control or other types or urological system compromise.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Nerve damage due to surgical trauma or presence of the device. Neurological difficultiesincluding but not limited to bowel and/or bladder dysfunction, impotence, retrograde IFU 0029 Rev A 03/2023 ejaculation, radicular pain, paralysis temporary or permanent, dural tears, tethering, compromise or compression of nerves in scar tissue and/or pain, muscle weakness, and paresthesias or other types of serious injury.
- Cerebral spinal fluid leakage.
- Spinal cord impingement or damage.
- Vascular damage could result in fatal bleeding. Malpositioned implants adjacent to large arteriesor veins could erode these vessels and cause catastrophic bleeding in the late post-operativeperiod.
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis,pneumonia, etc.
- Change in mental capacities
- Death.

Warnings

- Use of supplemental fixation is required. Safety and effectiveness have not been established forthe use of the Anatomic PEEK™ implants without the use of internal fixation systems.
- The Anatomic PEEK™ implants are sterile. Resterilization of the implant is not permitted.
- The Anatomic PEEK™ instruments are not sterile and must be thoroughly cleaned and sterilizedbefore use according to the complete instructions included in the “How Supplied” section.
- This product must be used in conjunction with autograft and/or allograft comprised ofcancellous and/or corticocancellous bone graft.
- Do not implant titanium and stainless-steel components together.
- Components of this system can be used with anterior or posterior supplemental fixation.

Precautions

- Use of the Anatomic PEEK™ system should only be undertaken after the surgeon has becomethoroughly knowledgeable about spinal anatomy and biomechanics; has had experience withthe implantation procedures and has had hands-on training in the use of this device, and hasread and understood the Package Insert and Surgical Technique. The latest revision of theSurgical Technique is available from Nanovis Spine, at 5865 East State Rd 14 Columbia City, IN46725, 1-877-907-6266.
- Correct selection of the appropriate implant size is extremely important.
- Excessive loads such as excessive torque applied to long-handled insertion tools attached tothreaded insertion holes or direct application of loads to the threads or a small area of theimplant can split or fracture the cage implants. Split or fractured cages should be removed andreplaced.
- Surgical implants must never be reused or reimplanted. Even though the device appearsundamaged, it may have small defects and internal stress patterns which may lead to earlybreakage.
- Safety and effectiveness have not been established in patients with the following conditions:morbid obesity or pregnancy.
- As the number of previous surgeries at the involved spinal level increases, the potential forintra-operative dural tears increases.
- Implant components can break when subjected to the increased loading associated withdelayed union or nonunion.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results.

Selection of the proper implant for each patient is crucial to the success of the procedure. Implants are subject to repeated stresses in use, and the strength of the implant is limited.

Performance of the implant when subjected to in vitro (laboratory) testing, for example fatigue testing, does not guarantee the same performance after implantation, unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant.

Preoperative and operating procedures, including knowledge of surgical techniques, adequate reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

The important medical information given in this document should be conveyed to the patient.

! USA For US audiences only.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Important Information on the Grafton™ DBM

Indications
Grafton™ DBF can be used in orthopedic or reconstructive bone grafting procedures. The product can also be used in bone grafting procedures in combination with autologous bone or other forms of allograft bone, or alone as a bone graft.

Contraindications
The presence of infection at the transplantation site is a contraindication for the use of this allograft.

Caution
This allograft may contain trace amounts of antibiotics (gentamicin), antiseptic (povidone-iodine) and alcohol solutions. Caution should be exercised if the patient is allergic to these antibiotics or chemicals.

Precautions
Extensive donor blood serum testing, medical and social history screening procedures, and tissue microbiological testing were used in the qualification of tissue donors. Despite the viral inactivation and extensive tissue donor selection and qualification processes used in providing this tissue graft (see DONOR SCREENING AND TESTING), transmission of a communicable disease is still possible. Bacterial infection at the graft site may also occur. Adverse outcomes potentially attributable to Grafton™ DBF must be reported promptly to Medtronic. If injecting Grafton™ DBF into the defect site, precaution should be taken not to:

- over-pressurize the delivery device, as this may lead to extrusion of the device beyond the site of its intended application and damage to the surrounding tissues.
- over-pressurize the defect site, as this may lead to fat embolization or embolization of the device material into the bloodstream.

For a complete list of indications, safety, and warnings for Grafton™ DBF, please visit https://manuals.medtronic.com/content/dam/emanuals/spinal/M708348B464EGraftonDBFDemineralizedBoneMatrix DBMFibersRevD.pdf

For more information visit Medtronic.com or call (800) 933-2635.

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Memphis, TN 38132

Nanovis Spine, LLC.
5865 East State Road 14
Columbia City, Indiana 46725
Phone: 1-877-907-6266

Consult instructions for use at this website
www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser.
For best results, use Adobe Acrobat™ Reader with the browser.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

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